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March 9, 2011

5. 510(k) SUMMARY

DATE: March 9, 2011

SUBMITTER: B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Nancy Skocypec, Regulatory Affairs Specialist
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DEVICE NAME: Prontosan® Wound Irrigation Solution

**COMMON OR
USUAL NAME:** Wound Cleanser, Wound Dressing, Drug

**DEVICE
CLASSIFICATION:** Product Code FRO, Unclassified

PREDICATE DEVICES: Prontosan® Wound Irrigation Solution, B. Braun Medical, Inc., K072876, Class II, Product Code FRO, Unclassified
Prontosan® Wound Gel, B. Braun Medical, Inc., K101882, Class II, Product Code FRO, Unclassified

DESCRIPTION: The subject device of this submission is Prontosan® Wound Irrigation Solution indicated for over-the-counter use. Prontosan Wound Irrigation Solution is currently cleared in a prescription use only version.

Prontosan Wound Irrigation Solution is a clear, colorless and nearly odorless liquid intended for the management of wounds. The mechanical action of fluid moving across the wound provides the mechanism of action and aids in the removal of foreign material such as dirt and debris. The subject device is offered in 40 ml ampoules and 350 ml squeeze bottles with screw caps.

The solution contains polyhexanide, a preservative that inhibits microbial growth within the product.

INTENDED USE: Prontosan® Wound Irrigation Solution for over-the-counter use, is intended for cleaning wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations and minor burns.

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**SUBSTANTIAL
EQUIVALENCE:**

Two predicate devices are utilized for substantial equivalence, Prontosan® Wound Irrigation Solution (K072876) and Prontosan® Wound Gel (K101882).

The proposed Prontosan Wound Irrigation Solution, indicated for over-the-counter use, is identical to the product indicated for prescription use in the original Prontosan Wound Irrigation Solution submission, K072876. Both of these solutions have identical formulations and they are processed and filled in the same manner.

The proposed Prontosan Wound Irrigation Solution, indicated for over-the-counter use, is similar to Prontosan Wound Gel (K101882). The active ingredients for both products are identical. Prontosan Wound Gel is cleared for both over-the-counter and prescription indications.

**NON-CLINICAL
TESTING:**

Antimicrobial Effectiveness Testing was conducted with the proposed device according to USP <51> category 2. Gram positive and gram negative bacteria and fungi typically found in a wound bed were used in this testing. The proposed device was tested against the following bacteria: *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, *methicillin-resistant Staphylococcus aureus*, *Vancomycin-resistant enterococcus*, *Serratia marcescens*, *Acinetobacter baumannii*, *Proteus mirabilis*, *Staphylococcus epidermidis*, *Enterococcus faecalis* and *Enterobacter cloacae* and the following fungi: *Candida albicans*, and *Aspergillus brasiliensis (niger)*. The test results demonstrate the effectiveness of Prontosan Wound Irrigation Solution to inhibit the growth of microorganisms within the product.

CONCLUSION:

The Prontosan Wound Irrigation Solution device indicated for over-the-counter use, is identical to the predicate Prontosan Wound Irrigation Solution device indicated for prescription use. The proposed Prontosan Wound Irrigation Solution indicated for over-the-counter use and Prontosan Wound Gel have similar labeling, including the indication for over-the-counter use.

B.Braun believes the Prontosan Wound Irrigation Solution indicated for over-the-counter use is substantially

equivalent to the currently cleared and marketed
Prontosan® Wound Irrigation Solution for prescription use
and Prontosan® Wound Gel for over-the-counter use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

B. Braun Medical, Inc.
% Ms. Nancy Skocypec
Regulatory Affairs Specialist
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

APR - 6 2011

Re: K110744
Trade/Device Name: Prontosan[®] Would Irrigation Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 30, 2010
Received: October 1, 2010

Dear Ms. Skocypec:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

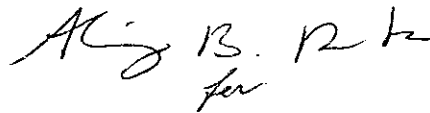
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish underneath.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

March 9, 2011

4. INDICATIONS FOR USE STATEMENT

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510(k) Number (if known): K110744

Device Name: Prontosan® Wound Irrigation Solution

Indications For Use:

Prontosan® Wound Irrigation Solution is intended for cleaning wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations and minor burns.

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krone for MXM
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

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